K043425

FEB 2 8 2005

SHEATHING
SHEATHES
TECHNOLOGIES ™

510 (k) Summary

Application date: 12/09/04

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Re: **510(k) Notification**

Dear Sir or Madam:

This letter along with the attached materials is to notify your office of the intention of Sheathing Technologies, Inc. to market the following device(s) starting (90) days from this date.

Trade Name – Sheathes Needle Guide System

Common Name – Needle Guide for Ultrasound

Classifications Name – Diagnostic Ultrasound Transducer

Product Equivalence: The Needle Guide system covered in this application is substantially equivalent to the SiteRite Needle Guide marketed by Bard Access Systems of Salt Lake City, Utah, and the Maggi Needle Guide system marketed by Civco Medical Systems Co., Inc of Kalona, Iowa.

	Site Rite Needle Guide	Civco Maggi II Plus
510(k) Number	K931403 (Dymax – modification)	K882383
510K Approval Date	07/27/1993	11/28/1988

Labeling for Predicate Devices is contained in Appendix C.

SHEATHING TECHNOLOGIES, INC.
18431 TECHNOLOGY DRIVE
MORGAN HILL, CA 95037
PHONE: 1-800-873-3776 FAX: 1-877-244-5048
WEBSITE: http://www.sheathingtechnologies.com E-MAIL: sheathes@msn.com

2. Design, Application Method – Clip on plastic components providing various access depths and angles, and supporting various size needles.

3. Materials: Thermoplastic disposable components – Nylon and ABS

4. Sterility: Single use components provided presterilized.

Summary description: The Sheathes Needle Guide system consists of 4 primary components which are used to provide alignment with an ultrasound transducer, in order to guide a needle, biopsy device, or other interventional tool in relation to the ultrasound image. Three components (a transducer cover, a guide clip, and retainer clip) are single use disposable, while the fourth component, the adapter, is a reusable component, providing a system interface to various transducers.

Intended use of device: The Sheathes Needle Guide provides guidance for a needle, catheter, biopsy apparatus, or other interventional device by positioning it relative to the ultrasound transducer and the resulting image during a diagnostic ultrasound procedure in order to perform a visually guided biopsy or needle placement.

In compliance with regulations according the Safe Medical Devices Act, information regarding this product will be made available to interested products upon request.

We believe this document provides the necessary information for your office to determine whether our device is equivalent to a legally marketed predicate device. All this information is deemed to be confidential and may not be released without consent of Sheathing Technologies.

Thank you for your assistance and should you have any questions, please contact us at (408) 782-2720.

Sincerely,

Lawrence S. Polayes
CEO
Sheathing Technologies, Inc.
18431 Technology Drive
Morgan Hill, CA 95037
(408) 782-2720 Phone
(408) 778-8523 FAX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2005

Mr. Lawrence S. Polayes
CEO
Sheathing Technologies, Inc.
18431 Technology Drive
MORGAN HILL CA 95037

Re: K043425
Trade/Device Name: Sheathes Needle Guild System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: February 7, 2005
Received: February 14, 2005

Dear Mr. Polayes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): _____

Device Name: Sheathes Needle Guide System

Indications for Use:

The Sheathes Needle Guide provides guidance for a needle, catheter, biopsy apparatus, or other interventional device by positioning it relative to the ultrasound transducer and the resulting image during a diagnostic ultrasound procedure in order to perform a biopsy or precise needle placement.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043425